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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,175	09/04/2001	Nobuhiko Ogura	Q65952	9850

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/944,175

Applicant(s)

OGURA, NOBUHIKO

Examiner

Christopher M. Gross

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 10-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Responsive to communications entered 8/10/2006. Examiner on the instant case has changed (see contact information below). Claims 1,2,4-8,10-22 are pending. Claims 3, 9, 23-14 are canceled. Claims 1,2,4-8,10-22 are examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2006 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Japanese patent 2000-267449 filed 09/04/2000. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Withdrawn Rejections -35 USC § 112

The rejection of claims 1, 2, 4-8, and 10-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments and arguments.

Maintained Rejections - 35 USC § 112

Claims 1, 2, 4-8, and 10-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of analyzing biochemical wherein the steps of a) fixing the probes on a substrate, i.e. a "non-covalent attachment" of the probe onto the substrate, and b) fractionating combined bodies of the probe and capture target, i.e. the complex of both the probe and capture target are "separated" from the substrate (see instant specification pg. 21-23 and 40-43), does not reasonably provide enablement for the method of analyzing biochemical wherein the steps of a) fixing the probes on a substrate, i.e. "covalent attachment" of the probe onto the substrate, and b) fractionating combined bodies of the probe and capture target, i.e. the complex of both the probe and capture target are "separated" from the substrate. In addition the instant specification does not provide a specific definition for the step of fixing the probes on a substrate such that the broadest reasonable interpretation, i.e. the scope of this step, of this step would include both "non-covalent attachment" of the probe onto the substrate and "covalent attachment" of the probe onto the substrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is a scope of enablement rejection (see MPEP § 2164.08 and *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993)).

Response to Arguments

Applicant argues, see p 8 (10/18/2006) that methods for covalent attachment of DNA and RNA were known at the time the invention was made.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

The Examiner concedes that robust methods for covalently immobilizing nucleic acids were well developed at the time the invention was made, however, the thrust of the enablement rejection in the Office Action mailed 4/10/2006 was not directed to covalent immobilization of nucleic acid probes, but rather *fractionation* of the covalently immobilized combined body of a probe plus the captured target (or substance derived from a living organism other than the target).

As mentioned in the last Office Action, p 5, like the instant invention, the method of capillary affinity gel electrophoresis, according to Muscate et al (1998 Anal. Chem 70:1419-1424) comprises covalent immobilization of complementary nucleic acid probes to a polymeric backbone (i.e. fixing a probe). Due to said covalent immobilization, however, electrophoretic migration only occurs with the target species, not the fixed probe and further because fractionation requires migration, the probe cannot be fractionated

In other words, a covalently immobilized probe will not move (migrate) in concert with its corresponding target.

Also, as mentioned in the last Office Action, p 6, Applicant does not provide any examples of covalently immobilized probes, which migrate along with their corresponding targets which are capable of being fractionated, such as set forth in lines 5-7 of claim 1.

And, according to *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), “[n]aturally, the specification must teach those of skill in the art how to make and use the invention as broadly as it is claimed.” Emphasis added. The disclosure does not teach fractioning of covalently immobilized probes plus their corresponding targets (or substance derived from a living organism other than the target).

Maintained Rejections - 35 USC § 102

Claims 1, 2, 5, 11, 13, 15, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishii et al. (*Nucleic Acids Res.*, 1997, 25(17), pgs. 3550-3551).

Response to Arguments

Applicant argues that not all elements are taught by Ishii et al. Applicant's arguments have been considered but they are not persuasive for the following reasons.

Specifically, applicant argues, see p 9 (8/10/2006) that Ishii et al do not teach fractioning the target, however applicant's attention is respectfully invited to figure 2b where, Ishii et al teach fractionation in terms of a electrophoretic mobility shift assay. In particular, Ishii et al teach monoclonal antibodies (probes) capable of supershifting the suspected DNA binding protein Rbf1p (target) from *Candida albicans*. Supershifting represents a type of fractionation because the Rbf1p immnocomplex migrates slower than Rbf1p by itself.

Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., fractioning the target) are not recited in the rejected claim(s).

Art Unit: 1639

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The fractionation step in lines 5-8 of claim 1 is drawn to fractioning a combined body of the probe, the captured target and a substance derived from a living organism other than the captured target, *not* to fractioning the target by itself.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

JON EPPERSON, PH.D.
PATENT EXAMINER

A handwritten signature in black ink, appearing to be 'J. Epperson', written over the printed name.